

FORM PTO - 1449

SECOND SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: LEX-002C1

APPLICANT(S): Gillies et al.

SERIAL NO.: 10/005,212

FILING DATE: December 4, 2001 GROUP: 1646

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## U.S. PATENT DOCUMENTS

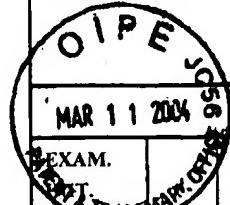
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Pm	A60	4,703,008	10/27/87	Lin			
	A61	5,441,868	8/15/95	Lin			
	A62	5,547,933	8/20/96	Lin			
	A63	5,618,698	4/8/97	Lin			
	A64	5,624,821	4/29/97	Winter et al.			
	A65	5,679,543	10/21/97	Lawlis			
	A66	5,688,679	11/18/97	Powell			
	A67	5,756,349	5/26/98	Lin			
	A68	5,856,298	1/5/99	Strickland			
	A69	5,888,772	3/30/99	Okasinski et al.			
	A70	5,955,422	9/21/99	Lin			
	A71	6,231,536	5/15/01	Lentz			
	A72	6,284,536	9/4/01	Morrison et al.			
	A73	6,335,176	1/1/02	Inglese et al.			
	A74	6,340,742	1/22/02	Burg et al.			
	A75	6,444,792	9/3/02	Gray et al.			
	A76	6,475,717	11/5/02	Enssle et al.			
	A77	6,485,726	11/26/02	Blumberg et al.			
	A78	6,506,405	1/14/03	Desai et al.			
	A79	6,583,272	6/24/03	Bailon			
	A80	6,586,398	7/1/03	Kinstler et al.			
	A81	6,617,135	9/9/03	Gillies et al.			
	A82	2001/0053539	12/20/01	Lauffer et al.			
	A83	2002/0081664	6/27/02	Lo et al.			
	A84	2002/0142374	10/3/02	Gallo et al.			
	A85	2002/0147311	10/10/02	Gillies et al.			
	A86	2002/0192222	12/19/02	Blumberg et al.			
	A87	2002/0193570	12/19/02	Gillies et al.			

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EXAM. INIT.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
PM	A88	2003/0003529	1/2/03	Bayer		
	A89	2003/0044423	3/6/03	Gillies et al.		
	A90	2003/0049227	3/13/03	Gillies et al.		
	A91	2003/0105294	6/5/03	Gillies et al.		
	A92	2003/0012789	1/6/03	Blumberg et al.		
	A93	2003/0157054	8/21/03	Gillies et al.		
	A94	2003/0166163	9/4/03	Gillies		
	A95	2003/0166877	9/4/03	Gillies et al.		

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## FOREIGN PATENT DOCUMENTS

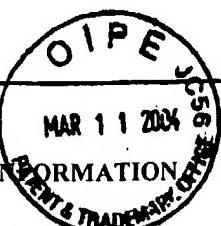
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PM	B88	0 640 619 A1	3/1/95	EP				Y
	B89	0 668 353 A1	8/23/95	EP				Y
	B90	1 088 888 A1	4/4/01	EP				Y
	B91	WO 94/24160	10/27/94	PCT				Y
	B92	WO 94/25055	11/10/94	PCT				Y
	B93	WO 97/43316	11/20/97	PCT				Y
	B94	WO 99/66054	12/23/99	PCT				Y
	B95	WO 00/24893	5/4/00	PCT				
	B96	WO 00/68376	11/16/00	PCT				Y
	B97	WO 01/36489	5/25/01	PCT				Y
	B98	WO 01/58957	8/16/01	PCT				
	B99	WO 02/02143	1/10/02	PCT				
	B100	WO 02/066514	8/29/02	PCT				Y
	B101	WO 02/072605	9/19/02	PCT				
	B102	WO 02/079232	10/10/02	PCT				
	B103	WO 02/079415	10/10/02	PCT				
	B104	WO 02/090566	11/14/02	PCT				

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EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME		CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
PM	B105	WO 03/048334	6/12/03	PCT				
PM	B106	WO 03/077834	9/25/03	PCT				Y

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INIT. OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)

PM	C170	Angal et al., (1993), "A Single Amino Acid Substitution Abolishes the Heterogeneity of Chimeric Mouse/Human (IgG4) Antibody," <u>Molecular Immunology</u> , 30(1):105-108.
	C171	Batra et al., (1993), "Insertion of Constant Region Domains of Human IgG1 into CD4-PE40 Increases Its Plasma Half-Life," <u>Mol. Immunol.</u> , 30(4):379-386.
	C172	Becker et al., (1996), "Long-lived and Transferable Tumor Immunity in Mice after Targeted Interleukin-2 Therapy," <u>J Clin Invest.</u> , 98(12):2801-2804.
	C173	Becker et al., (1996), "T Cell-mediated Eradication of Murine Metastatic Melanoma Induced by Targeted Interleukin-2 Therapy," <u>J Exp. Med.</u> , 183(50):2361-6.
	C174	Bitonti et al., (2002), "Transepithelial Absorption of an Erythropoietin-Fc Fusion Protein After Delivery to the Central Airways," <u>Respiratory Drug Delivery</u> , 8:309-312.
	C175	Boissel et al., (1993), "Erythropoietin Structure-Function Relationships: Mutant Proteins that Test a Model of Tertiary Structure," <u>The Journal of Biological Chemistry</u> , 268(21):15983-15993.
	C176	Briggs et al., (1974), "Hepatic Clearance of Intact and desialylated Erythropoietin," <u>American Journal of Physiology</u> , 227(6):1385-1388.
	C177	Chuang et al., (1994), "Alteration of Lymphocyte Microtubule Assembly, Cytotoxicity, and Activation by the Anticancer Drug Taxol," <u>Cancer Research</u> , 54:1286-1291.
	C178	Cruse et al., (1995), <u>Illustrated Dictionary of Immunology</u> , CRC Press, NY, p.156-7.
	C179	Darling et al., (2002), "Glycosylation of Erythropoietin Affects Receptor Binding Kinetics: Role of Electrostatic Interactions," <u>Biochemistry</u> , 41:14524-14531.
	C180	Davis et al., (2003), "Immunocytokines: Amplification of Anti-cancer Immunity," <u>Cancer Immunol. Immunother.</u> , 52:297-308.
	C181	Dolman et al., (1998), "Suppression of Human Prostate Carcinoma Metastases in Severe Combined Immunodeficient Mice by Interleukin 2 Immunocytokine Therapy," <u>Clin Cancer Res.</u> , 4(10):2551-7.
	C182	Duncan et al., (1988), "The Binding Site for Clq on IgG," <u>Nature</u> , 332:738-740.
	C183	Egrie et al., (2001), "Development and Characterization of Novel Erythropoiesis Stimulating Protein (NESP)," <u>Nephrol. Dial. Transplant.</u> , 16:3-13.
	C184	Elliott et al., (1997), "Mapping of the Active Site of Recombinant Human Erythropoietin," <u>Blood</u> , 89(2):493-502.
	C185	Fibi et al., (1995), "N- and O-Glycosylation Muteins of Recombinant Human Erythropoietin Secreted From BHK-21 Cells," <u>Blood</u> , 85(5):1229-1236.

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EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
PM	C186	Frost et al., (1997), "A Phase I/IB Trial of Murine Monoclonal Anti GD2 Antibody 14.G2a Plus Interleukin-2 in Children with Refractory Neuroblastoma," <u>Cancer</u> , 80:317-33.					
	C187	Gan et al., (1999), "Specific enzyme-linked Immunosorbent Assays for Quantitation of Antibody-cytokine Fusion Proteins," <u>Clin. Diagn. Lab. Immunol.</u> , 6(2):236-42.					
	C188	Gillies et al., (1991), "Expression of Genetically Engineered Immunoconjugates of Lymphotoxin and a Chimeric Anti-ganglioside GD2 Antibody," <u>Hybridoma</u> , 10(3):347-56.					
	C189	Gillies et al., (2002), "Bi-functional Cytokine Fusion Proteins for Gene Therapy and Antibody-targeted Treatment of Cancer," <u>Cancer Immunol. Immunother.</u> , 51(8):449-60.					
	C190	Gillies et al., (2002), "Improved Circulating Half-life and Efficacy of an Antibody-interleukin 2 Immunocytokine Based on Reduced Intracellular Proteolysis," <u>Clin. Cancer Res.</u> , 8(1):210-6.					
	C191	Greene et al., (1975), Neuronal Properties of Hybrid Neuroblastoma X Sympathetic Ganglion Cells," <u>Proc. Natl. Acad. Sci. USA</u> , 72(12):4923-4927.					
	C192	Hammerling et al. (1996), "In Vitro Bioassay for Human Erythropoietin based on Proliferative Stimulation of an Erythroid Cell Line and Analysis of Carbohydrate-dependent Microheterogeneity," <u>Journal of Pharmaceutical and Biomedical Analysis</u> , 14:1455-1469.					
	C193	Hank et al., (1996), "Activation of Human Effector Cells by a Tumor Reactive Recombinant Anti-ganglioside GD2 Interleukin-2 Fusion Protein (ch14.18-IL2)," <u>Clin Cancer Res.</u> , 2(12):1951-9.					
	C194	Hank et al., (2003), "Determination of peak serum levels and immune response to the humanized anti-ganglioside antibody-interleukin-2 immunocytokine," <u>Methods Mol. Med.</u> , 85:123-31.					
	C195	Haraguchi, (1994), "Isolation of GD3 Synthase Gene by Expression Cloning of GM3 α-2,8-sialyltransferase Cdna using anti-GD2 Monoclonal Antibody," <u>Proc. Natl. Acad. Sci. USA</u> , 91(22):10455-9.					
	C196	Harris, (1995), "Processing of C-terminal Lysine and Arginine Residues of Proteins Isolated from Mammalian Cell Culture," <u>J. Chromatogr. A</u> , 705:129-134.					
	C197	Harvill et al., (1995), "An IgG3-IL2 Fusion Protein Activates Complement, Binds FcYRI, Generates LAK Activity and Shows Enhanced Binding to the High Affinity IL-2R," <u>Immunotech.</u> , 1:95-105.					
	C198	Hezareh et al., (2001), "Effector Function Activities of a Panel of Mutants of a Broadly Neutralizing Antibody against Human Immunodeficiency Virus Type 1," <u>J. Virol.</u> , 75(24):12161-8.					
	C199	Idusogie et al., (2000), "Mapping of the C1q Binding Site on Rituxan, a Chimeric Antibody with a Human IgG1 Fc," <u>J. Immunol.</u> , 164(8):4178-4184.					
	C200	Imboden et al., (2001), "The Level of MHC Class I Expression on Murine Adenocarcinoma Can Change the Antitumor Effector Mechanism of Immunocytokine Therapy," <u>Cancer Res.</u> , 61(4):1500-7.					
	C201	Kato et al., (1997), "Mechanism for the Nonlinear Pharmacokinetics of Erythropoietin in Rats," <u>The Journal of Pharmacology and Experimental Therapeutics</u> , 283:520-527.					
	C202	Kato et al., (1998), "Pharmacokinetics of Erythropoietin in Genetically Anemic Mice," <u>Drug Metabolism and Disposition</u> , 26:126-131.					

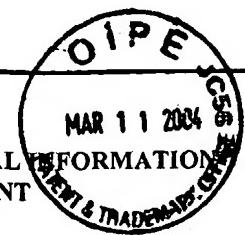
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PM	C203		Kitamura et al. (1989), "Establishment and Characterization of a Unique Human Cell Line that Proliferates Dependently on GM-CSF, IL-3, or Erythropoietin," <u>Journal of Cellular Physiology</u> , 140:323-334.			
	C204		Kushner et al., (2001), "Phase II Trial of the Anti-GD2 Monoclonal-macrophage-colony-stimulating Factor for Neuroblastoma," <u>J. Clin. Oncol.</u> , 19:4189-94.			
	C205		Locatelli et al., (2001), "Darbe poe tin alfa Amgen," <u>Current Opinion in Investigational Drugs</u> , 2:1097-1104.			
	C206		Lode et al., (2000), "What to do with Targeted IL-2," <u>Drugs Today</u> , 36(5):321-36.			
	C207		Lode et al., (2000), "Melanoma Immunotherapy by Targeted IL-2 Depends on CD4(+) T-cell Help Mediated by CD40/CD40L Interaction," <u>J. Clin. Invest.</u> , 105(11):1623-30.			
	C208		Macdougall, (2002), "Optimizing the Use of Erythropoietic Agents—Pharmacokinetic and Pharmacodynamic Considerations," <u>Nephrol. Dial. Transplant.</u> , 17:66-70.			
	C209		Metelitsa et al., (2002), "Antidisialoganglioside/granulocyte Macrophage-colony-stimulating Factor Fusion Protein Facilitates Neutrophil Antibody-dependent Cellular Cytotoxicity and Depends on Fc $\gamma$ RII (CD32) and Mac-1 (CD11b/CD18) for Enhanced Effector Cell Adhesion and Azurophil Granule Exocytosis," <u>Blood</u> , 99(11):4166-73.			
	C210		Mueller et al. (1997), "Humanized Porcine VCAM-specific Monoclonal Antibodies with Chimeric IgG2/G4 Constant Regions Block Human Leukocyte Binding to Porcine Endothelial Cells," <u>Molecular Immunology</u> , 34(6):441-452.			
	C211		Mullins et al. (1997), "Taxol-mediated Changes in Fibrosarcoma-induced Immune Cell Function: Modulation of Antitumor Activities," <u>Cancer Immunol. Immunother.</u> , 45:20-28.			
	C212		Naramura et al., "Mechanisms of Cellular Cytotoxicity Mediated by a Recombinant Antibody-IL2 Fusion Protein against Human Melanoma Cells," <u>Immunology Letters</u> , 39(1):91-9.			
	C213		Neal et al. (2003), "NXS2 Murine Neuroblastomas Express Increased Levels of MHC Class I Antigens upon Recurrence Following NK-dependent Immunotherapy," <u>Cancer Immunol. Immunother.</u> , 53:41-52.			
	C214		Ngo et al., (1994), "The Protein Folding Problem and Tertiary Structure Prediction," pp. 433-440 and 492-495, Birkhauser Boston.			
	C215		Niethammer et al., (2002) "An oral DNA Vaccine against Human Carcinoembryonic Antigen (CEA) Prevents Growth and Dissemination of Lewis Lung Carcinoma in CEA Transgenic Mice," <u>Vaccine</u> , 20:421-9.			
	C216		Niethammer et al., (2001) "Targeted Interleukin 2 Therapy Enhances Protective Immunity Induced by an Autologous Murine Melanoma," <u>Cancer Res.</u> , 61(16):6178-84.			
	C217		Nimtz et al., (1993) Structures of Sialylated Oligosaccharides of Human Erythropoietin Expressed in Recombinant BHK-21 Cells," <u>Eur. J. Biochem.</u> , 213:39-56.			
	C218		Pancook et al., (1996), "Eradication of Established Hepatic Human Neuroblastoma Metastases in Mice with Severe Combined Immunodeficiency by Antibody-targeted Interleukin-2," <u>Cancer Immunol. Immunother.</u> , 42(2):88-92.			

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P M	C219		Park et al., (2000), "Efficiency of Promoter and Cell line in High-level Expression of Erythropoietin," <i>Biotechnol. Appl. Biochem.</i> , 32:167-172.			
	C220		Reisfeld et al., (1996), "Antibody-interleukin 2 Fusion Proteins: A New Approach to Cancer Therapy," <i>J Clin Lab Anal.</i> , 10(3):160-6.			
	C221		Reisfeld et al., (1996), "Involvement of B Lymphocytes in the Growth Inhibition of Human Pulmonary Melanoma Metastases in Athymic nu/nu Mice by an Antibody-lymphotoxin Fusion Protein," <i>Cancer Res.</i> , 56(8):1707-12.			
	C222		Ruehlmann et al., (2001), "MIG (C1XCL9) Chemokine Gene Therapy Combines with Antibody-cytokine Fusion Protein to Suppress Growth and Dissemination of Murine Colon Carcinoma," <i>Cancer Res.</i> , 61(23):8498-503.			
	C223		Sabzevari et al., (1994), "A Recombinant Antibody-interleukin 2 Fusion Protein Suppresses Growth of Hepatic Human Severe Combined Immunodeficiency Mice," <i>Proc. Natl. Acad. Sci. USA</i> , 91(20):9626-30.			
	C224		Seidenfeld et al., (2001), "Epoietin Treatment of Anemia Associated with Cancer Therapy: A Systematic Review and Meta-analysis of controlled Clinical Trials," <i>Journal of National Cancer Institute</i> , 93:1204-1214.			
	C225		Shinkawa et al., (2003), "The Absence of Fucose but Not the Presence of Galactose or Bisecting N-Acetylglucosamine of Human IgG1 Complex-type Oligosaccharides Shows the Critical Role of Enhancing Antibody-dependent Cellular Cytotoxicity," <i>J. Biol. Chem.</i> , 278:3466-3473.			
	C226		Spiekermann et al., (2002), "Receptor-mediated Immunoglobulin G Transport Across Mucosal Barriers in Adult Life: Functional Expression of FcRn in the Mammalian Lung," <i>J. Exp. Med.</i> , 196:303-310.			
	C227		Strom et al., (1996), "Therapeutic Approach to Organ Transplantation," <i>Therapeutic Immunology</i> , Blackwell Science, Chapter 36, pp. 451-456.			
	C228		Syed et al., (1998), "Efficiency of Signaling through Cytokine Receptors Depends Critically on Receptor Orientation," <i>Nature</i> , 395:511-516.			
	C229		Thommesen et al., (2000), "Lysine 322 in the Human IgG3 CH2 Domain is Crucial for Antibody Dependent Complement Activation," <i>Mol. Immunol.</i> , 37(16):995-1004.			
	C230		Wells, (1990), "Additivity of Mutational Effect in Proteins," <i>Biochemistry</i> , 29(37):8509-8517.			
	C231		Wen et al., (1993), "Erythropoietin Structure-Function Relationships: High Degree of Sequence Homology Among Mammals," <i>Blood</i> , 82(5):1507-1516.			
	C232		Xiang et al., (1998), "Induction of Persistent Tumor-protective Immunity in Mice Cured of Established Colon Carcinoma Metastases," <i>Cancer Research</i> , 58(17):3918-3925.			
	C233		Xiang et al., (1999) "T Cell Memory against Colon Carcinoma is Long-lived in the Absence of Antigen," <i>J. Immunol.</i> , 163(7):3676-83.			
	C234		Xiang et al., (2001), "A Dual Function DNA Vaccine Encoding Carcinoembryonic Antigen and CD40 Ligand Trimer induces T Cell-mediated Protective Immunity Against Colon Cancer in Carcinoembryonic Antigen-Transgenic Mice," <i>J. Immunol.</i> , 167(8):4560-5.			

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PM	C235	Xiang et al., (2001), "Protective Immunity Against Human Carcinoembryonic Antigen (CEA) Induced by an Oral DNA Vaccine in CEA-transgenic Mice," <u>Clin Cancer Res.</u> , 7(3 Supp):S856-S864.				
	C236	Xu et al., (1994), "Residue at Position 331 in the IgG1 and IgG4 CH2 Domains Contributes to Their Differential Ability to Bind and Activate Complement," <u>J. Biol. Chem.</u> , 269(5):3469-3474.				
	C237	Yu et al., (1998), "Phase I Trial of a Human-Mouse Chimeric Anti-Disialoganglioside Monoclonal Antibody ch14.18 in Patients with Refractory Neuroblastoma and Osteosarcoma," <u>J. Clin. Oncol.</u> , 16(6):2169-80.				
↓	C238	Zagozdzon et al. (1999), "Potentiation of Antitumor Effect of IL-12 in Combination with Paclitaxel in Murine Melanoma Model In Vivo," <u>International Journal of Molecular Medicine</u> , 4:645-648.				

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